

REGULATORY UNIT EVALUATION OF THE QUALITY ASSURANCE PROGRAM, REVISION 5A



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Office of Safety Regulation of the RPP-WTP Contractor

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PREFACE

The Department of Energy's (DOE) Richland Operations Office (RL) issued the *TWRS Privatization Request for Proposal* (RFP) for Hanford Tank Waste Remediation System (TWRS) Privatization in February 1996. Offerors were requested to submit proposals for the initial processing of the tank waste at Hanford. Some of this radioactive waste has been stored in large underground storage tanks at the Hanford Site since 1944. Currently, approximately 54 million gallons of waste containing approximately 240,000 metric tons of processed chemicals and 250 mega-curies of radionuclides are being stored in 177 tanks. These caustic wastes are in the form of liquids, slurries, saltcakes, and sludges. The wastes stored in the tanks are defined as high-level radioactive waste (10 CFR Part 50, Appendix F) and hazardous waste (Resource Conservation and Recovery Act).

The contract concept was for DOE to enter into a fixed-price contract for the contractor to build and operate a facility to treat the waste according to DOE specifications. The TWRS Privatization Program was divided into two phases, Phase I and Phase II. Phase I was a proof-of-concept/commercial demonstration-scale effort the objectives of which were to (a) demonstrate the technical and business viability of using privatized contractors to treat Hanford tank waste; (b) define and maintain adequate levels of radiological, nuclear, and process safety; (c) maintain environmental protection and compliance; and (d) substantially reduce life-cycle costs and time required to treat the tank waste. The Phase I effort consisted of two parts: Part A and Part B.

Part A consisted of a twenty-month development period to establish appropriate and necessary technical, operational, regulatory, business, and financial elements. This included identification by the TWRS Privatization Contractors and approval by DOE of appropriate safety standards, formulation by the Contractors and approval by DOE of integrated safety management plans, and preparation by the Contractors and evaluation by DOE of initial safety assessments. Of the twenty-month period, sixteen months were used by the Contractors to develop the Part-A products and four months were used by DOE to evaluate the products.

Part B was to consist of a demonstration period to provide tank waste treatment services by the TWRS Privatization Contractors who successfully completed Part A. Demonstration was to address a range of wastes representative of those in the Hanford tanks. Part B was to be 10 to 14 years in duration. Within Part B, wastes were to be processed during a 5- to 9-year period resulting in treatment of 6 to 13 percent of the Hanford tank waste.

Phase II was to be a full-scale production phase in which the remaining tank waste would be processed on a schedule that would accomplish removal from all single-shelled tanks by the year 2018. The objectives of Phase II were to a) implement the lessons learned from Phase I; and b) process all tank waste into forms suitable for final disposal.

In May 2000, DOE chose to terminate the privatization contract and seek new bidders under a different contract strategy. The program name was also changed from the Tank Waste Remediation System to the River Protection Project (RPP). The RPP is under the direction of the Office of River Protection, which was created by Congress in 1998 to assume programmatic responsibility for the entire Tank Waste Remediation System, including the waste treatment plant (WTP).

A key element of the River Protection Project Waste Treatment Plant (RPP-WTP) is DOE regulation of safety through a specifically chartered, dedicated Regulatory Unit (RU) at RL. This regulation by the RU is authorized by the document entitled *Policy for Safety Regulation of the RPP-WTP Contractor* (referred to as the Policy) and implemented through the document entitled *Memorandum of Agreement for the Execution of Safety Regulation of the RPP-WTP*

Contractor (referred to as the MOA). The Under Secretary of Energy; the Assistant Secretary for Environment, Safety and Health (ASEH); and the Assistant Secretary for Environmental Management (ASEM) signed the Policy. The MOA is signed by the ASEH and the ASEM. The nature and characteristics of this regulation are also specified in these documents. The MOA details certain interactions among RL, the ASEH, and the ASEM as well as their respective roles and responsibilities for implementation of this regulation.

The authority of the RU to regulate the RPP-WTP Contractor is derived solely from the terms of the RPP-WTP Contract. Its authority to regulate the Contractor on behalf of DOE is derived from the Policy. The nature and scope of this special regulation (in the sense that it is based on terms of a contract rather than formal regulations) is delineated in the MOA, the RPP-WTP Contract, and the documents, listed below, which are incorporated into the Contract. This special regulation by the RU in no way replaces any legally established external regulatory authority to regulate in accordance with duly promulgated regulations nor relieves the Contractor from any obligations to comply with such regulations or to be subject to the enforcement practices contained therein.

The Policy, the MOA, the RPP-WTP Contract, and the documents incorporated in the Contract define the essential elements of the regulatory program, which are being executed by the RU and to which the RPP-WTP Contractor must conform. The four radiological, nuclear and process safety-related documents incorporated in the Contract (and also incorporated in the MOA) are:

Concept of the DOE Process for Radiological, Nuclear, and Process Safety Regulation of the RPP Waste Treatment Plant Contractor, DOE/RL-96-0005,

DOE Process for Radiological, Nuclear, and Process Safety Regulation of the RPP Waste Treatment Plant Contractor, DOE/RL-96-0003,

Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the RPP Waste Treatment Plant Contractor, DOE/RL-96-0006, and

Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for the RPP Waste Treatment Plant Contractor, DOE/RL-96-0004.

The two non-radiological safety documents are:

Industrial Hygiene and Safety Regulatory Plan, RL/REG-2000-04, and

Regulatory Unit Position on Regulation of the Contractor's Industrial Hygiene and Safety Program, RL/REG-99-11.

In the execution of the regulatory program, the RU considers not only the relevant approaches and practices of DOE but also those of the U.S. Nuclear Regulatory Commission (NRC) and the Occupational Safety and Health Administration (OSHA). The Policy states that

"It is DOE's policy that the RPP-WTP Contractor activities be regulated in a manner that assures adequate safety by application of regulatory concepts and principles consistent with those of the Nuclear Regulatory Commission and the Occupational Safety and Health Administration."

To this end, the RU interacts with the NRC and the OSHA during development and execution of the regulatory program.

All documents issued by the Office of Safety Regulation of the RPP-WTP Contractor are available to the public through the DOE/RL Public Reading Room at the Consolidated Information Center, Room 1012, Richland, Washington. Copies may be purchased for a duplication fee.

RECORD OF REVISION

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Executive Summary

This document presents the Regulatory Unit's (RU's) evaluation of the latest revision (5A) of the Quality Assurance Program (QAP) for the River Protection Project - Waste Treatment Plant (RPP-WTP). The RU provided evaluation criteria to the Contractor and to the public, stakeholders, and Tribal Nations for information and comment before the start of the evaluation. The Contractor submitted Revision 5A to support construction. However, consistent with the schedules and program scope in place at the start of planning for the evaluation, the Regulatory Unit's (RU's) evaluation criteria addressed only elements of the QAP necessary for start of limited construction. Therefore, this evaluation considers only the adequacy of the QAP to support limited construction (see Question 00-QA-15, Appendix A).

During the RU's review, the Office of River Protection terminated the existing contract and started a process to select a new RPP-WTP Contractor. Normally, the RU would provide questions to the Contractor and the Contractor would provide answers and/or QAP modifications to resolve the RU's concerns. While this process was not possible because of Contract termination, the RU completed its review of the latest revision in order to document issues for the new Contractor.

A new Contractor could not use the existing (Revision 5) or proposed (Revision 5A) version of the QAP without modification because it is specific to the organization and position responsibilities of the previous contractor. The RU intends that, by using this evaluation, the new Contractor can minimize the time required to document an acceptable QAP. In reviewing Revision 5A of the QAP, the RU found the following deficiencies that prevented approval of the proposed version of the QAP:

1. The QAP does not contain sufficient detail to identify how the criteria of 10 CFR 830.120 are satisfied during limited construction.
2. The QAP does not adequately identify the activities that will be placed under the QAP.
3. The QAP does not describe the graded approach in sufficient detail to judge the adequacy of the grading process.
4. The QAP is unclear in the extent to which the requirements of 10 CFR 830.120 are applied to dedicated commercial grade systems, structures, and components.
5. The QAP does not sufficiently describe project management and planning to comply with 10 CFR 830.120.

In addition, the RU identified several apparent inaccuracies and areas where limited changes would significantly improve the document's clarity. These are described in Appendix A.

The RU believes that correcting the noted deficiencies would not require extensive revisions to the QAP. Except as noted in the evaluation, the QAP contains an appropriate level of detail.

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REGULATORY UNIT EVALUATION OF THE QUALITY ASSURANCE PROGRAM, REVISION 5A

1.0 INTRODUCTION

In accordance with the requirements of its Contract,¹ the River Protection Project-Waste Treatment Plant (RPP-WTP) Contractor submitted within 45 days after Contract award an initial Quality Assurance Program (QAP) that supported performance of Part A activities. The initial QAP was BNFL-5193-QAP-01, *BNFL, Inc. Quality Assurance Program and Implementation Plan*. The U.S. Department of Energy (DOE), Office of Safety Regulation (Regulatory Unit, RU), used Revision 0 of RL/REG-96-01, *Guidance for Review of TWRS Privatization Contractor Initial Quality Assurance Program*, as the basis to review the Contractor's initial QAP and to develop comments. This review resulted in development of RL/REG-98-13, *DOE Regulatory Unit Evaluation Report of the BNFL, Inc. Quality Assurance Program and Implementation Plan*.

Section (b)(3) of 10 CFR Part 830.120, "Quality Assurance Requirements," (the Rule) states the following:

“A contractor may, at any time, make changes to an approved QAP. Changes made over the previous year shall be submitted annually to DOE for review. A submittal shall identify the changes, the pages affected, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of this section. Changes made to correct spelling, punctuation, or other editorial items do not require explanation.”

The Contractor submitted draft Revision 5A of its QAP (the Plan) for RU review on June 27, 2000.² This Evaluation Report (ER) documents the result of the RU's review of the Plan. The purpose of this ER is as follows:

- Describe the RU's evaluation process.
- Present the RU's questions from the evaluation process.
- Document the Contractor's response to the RU's questions. (Note: Because of the termination of the Contractor's Contract, this step in the review and evaluation process was not performed.)
- Document the conclusions of the RU evaluation.

¹ Contract No. DE-AC27-96RL13308 between DOE and BNFL Inc., dated August 24, 1998.

² CCN: 014254, Letter, S.R. Morgan, BNFL Inc., to D.C. Gibbs, DOE-RL, "Contract No. DE-AC27-96RL13308 – W375 – Quality Assurance Program, Revision 5A," dated June 27, 2000.

All letters and documents referenced in this ER are in the public record and are available through DOE, Richland Operations Office Public Reading Room at the Consolidated Information Center, 2710 University Drive, Richland, Washington.

2.0 REGULATORY INTERFACES

As the regulatory authority, the RU interfaced with several organizations to review the submittal and prepare this ER. The essential interfaces are as follows:

- Contractor's Manager of QA – The Manager, QA, is the head of the Contractor's organization responsible for preparing and maintaining the QAP. The Manager of QA is also the primary contact for questions on the Contractor's QAP, including the questions generated by this evaluation (see Appendix A).
- Tribal Nations – The RU informed staff of the Confederated Tribes and Bands of the Yakama Nation, the Nez Perce Tribe, and the Confederated Tribes of the Umatilla Indian Reservation that the Plan and the draft ER were available. At their request, copies of the Plan were provided to the Yakama Nation (the Yakama Nation reviewer had no comments).
- Stakeholders and the public – The Plan was made available to stakeholders and the public through the RU's website.³ Also, the draft of this ER was placed on the website for stakeholder and public review and comment.

3.0 REVIEW PROCESS

3.1 Review Approach

The RU developed RL/REG-96-01, Revision 1, *Guidance for the Review of the TWRS Privatization Quality Assurance Program*, to provide guidance on the content of the Contractor's Plan. Accordingly, RL/REG-96-01 was used as a guide during the review of the Plan.

The RU augmented the review guidance with RL/REG-2000-14, Quality Assurance Program and Implementation Plan (QAPIP) Planning Handbook (the Handbook).

The RU assembled a six-person review team to evaluate the Plan. The review team composition and expertise are presented in Appendix B. The reviewers systematically evaluated the Plan using the review guidance and process in the Handbook.

The purpose of this review was to determine whether the Contractor's Plan was adequate and whether it continued to satisfy applicable requirements. The Regulatory Official may use the results of the review as part of the subsequent readiness for limited construction decisions.

³ The RU's website is located at <http://www.hanford.gov/osr/osr.asp>.

3.2 Review Chronology

The chronology of the Contractor's submittal and the RU review is shown in Table 1.

Table 1. Review Chronology

Activity	Date
QAP, Revision 5A, received from the Contractor	June 27, 2000
QAP accepted by RU for detailed review	July 3, 2000
Comments received from the review team	July 20, 2000
QAP provided to Confederated Tribes and Bands of the Yakama Nation	July 24, 2000
Request to amend authorization basis pursuant to Revision 5A received from the Contractor (placed on RU website)	July 26, 2000
Reviewer Questions Issued	September 18, 2000
ER issued	October 6, 2000

4.0 REVIEW

The Handbook reflected the quality assurance requirements and criteria specified by law in 10 CFR 830.120, "Quality Assurance Requirements." The three general QA requirements and ten specific QA criteria that the Contractor's Plan was to address are:

- General QA Requirements [10 CFR 830.120(b)(1)]
 - Requirement 1: Demonstrating how the ten criteria will be satisfied
 - Requirement 2: Using the graded approach
 - Requirement 3: Using the appropriate standards
- QA Criteria That Apply to Work Management
 - Criterion 1: Quality Assurance Program [10 CFR 830.120(c)(1)(i)]
 - Criterion 2: Personnel Training and Qualification [10 CFR 830.120(c)(1)(ii)]
 - Criterion 3: Quality Improvement [10 CFR 830.120(c)(1)(iii)]
 - Criterion 4: Documents and Records [10 CFR 830.120(c)(1)(iv)]
- QA Criteria That Apply to Work Performance
 - Criterion 5: Work Processes [10 CFR 830.120(c)(2)(i)]
 - Criterion 6: Design [10 CFR 830.120(c)(2)(ii)]
 - Criterion 7: Procurement [10 CFR 830.120(c)(2)(iii)]
 - Criterion 8: Inspection and Acceptance Testing [10 CFR 830.120(c)(2)(iv)]
- QA Criteria That Apply to Work Assessment

Criterion 9: Management Assessment [10 CFR 830.120(c)(3)(i)]

Criterion 10: Independent Assessment [10 CFR 830.120(c)(3)(ii)].

The degree of the Plan's compliance with Contract Requirements, the three general QA requirements, and the ten QA criteria is discussed in the following sections. Attributes based on RL/REG-96-01 are shown for the 10 CFR 830.120 requirements and criteria. The attributes are not requirements; rather they serve as a guide for the reviewers.

4.1 Compliance with Contract Requirements

4.1.1 Requirements

QA Plan requirements are found in DOE/RL-96-0003, *DOE Process for Radiological, Nuclear, and Process Safety Regulation of the RPP Waste Treatment Plant Contractor*, which states, in part, the following:

“The Contractor's QA plan is adequate and has been implemented such that the intended quality will be assured in the safety-related portions of the design, construction, and pre-operational testing and that the quality assurance records will attest thereto.

This submittal package shall consist of the following documentation: 14) Description of QA program, including implementation procedures, employed during the design, and to be employed during construction, safety-related testing, and pre-operational testing.”

QA requirements are also addressed in DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the RPP Waste Treatment Plant Contractor*, which states, in part, the following:

“QA and Quality Control (QC) should be applied throughout all phases and to all activities associated with the facility as part of a comprehensive system to ensure with high confidence that all items delivered and services and tasks performed meet required standards.

The Contractor should use well proven and established techniques and procedures supported by quality assurance practices to provide high quality equipment and achieve high quality construction.”

The Contractor's Safety Requirements Document, Volume II, contains specific regulatory and contractual requirements for QA in Chapter 1.0, “Radiological, Nuclear and Process Safety Objectives,” and Section 7.3, “QA Program.”

4.1.2 Review Methodology and Conclusions

The reviewers evaluated the Contractor's Plan to determine whether the document complied with contract requirements and therefore was ready for detailed review. The reviewers determined

that the level of detail in the Plan was sufficient to justify proceeding to the in-depth review and evaluation of the Plan, the results of which are described in Sections 4.2 and 4.3 of this ER.

As described in Sections 4.2 and 4.3 and Appendix A of this ER, 15 questions were identified during the in-depth review and evaluation of the Contractor's Plan. These questions ranged in importance from minor concerns such as the need for clarification in terminology to significant issues such as an inadequate description of the graded approach. The questions are cited at the appropriate location in the evaluation except for Questions 00-QA-01, -02, -04, and -09, which are editorial.

On the basis of the evaluation described in Sections 4.2 and 4.3 of this ER, the reviewers concluded that areas within the Contractor's Plan were not fully acceptable (see the "Executive Summary").

4.2 General Quality Assurance Requirements

4.2.1 Requirements

10 CFR 830.120(b) has three general requirements, which are provided below, followed by the specific attributes the reviewers used during their evaluation of the Plan:

1. "A QAP shall include a discussion of how the criteria of paragraph (c) of this section will be satisfied."
 - Expect the Plan to identify the activities that will be placed under the QAP and to describe how QA measures will be used to achieve quality, including methods and systems to be used and identification of how the criteria are to be satisfied.
2. "The criteria of paragraph (c) of this section shall be applied using a graded approach."
 - Expect the Plan to describe the Contractor's rationale and method to discriminate between levels of analysis, documentation, and actions.
 - Expect the Plan to describe the method's application and its results.
 - Expect the rationale to include the following as they apply to the Contractor:
 - The relative importance to safety, safeguards, and security
 - The magnitude of any hazard involved
 - The life cycle stage of a facility
 - The programmatic mission of a facility
 - The particular characteristics of a facility
 - Any other relevant factor.
 - Expect the Contractor's graded approach to be based on prescribed facility-specific or activity-specific factors such as the following:

- Level of risk
 - Age, status, and condition of a facility or process
 - History of problems at a site or facility
 - Adequacy of existing safety documentation
 - Complexity of products or services involved.
- Judge the adequacy of the process applied to activities in the context of their importance to safety and quality.
 - Verify that the graded approach process is not used to obtain relief from (avoid) the requirements of 10 CFR 830.120.
3. “The contractor shall use appropriate standards, whenever applicable, to develop and implement its QAP.”
- Expect the Plan to describe the functions to be performed and the standards to which they conform.
 - Expect the Plan to identify the standards the Contractor used to develop the QAP and to justify their use.
 - Confirm the Contractor’s use of the Rule and QA-related top-level safety standards and principles.

4.2.2 Evaluation

The reviewers evaluated the Contractor’s Plan using the requirements described in Section 4.2.1, above. The reviewers found that the Contractor’s Plan did not fully meet the general requirements. Evaluations of the attributes are discussed below (citations refer to the applicable section of the Plan):

1. The reviewers evaluated the extent to which the Plan discussed the methods and systems to be used and how the criteria of 10 CFR 830.120 are to be satisfied. The Plan does not contain sufficient detail to specifically identify how the criteria of 10 CFR 830.120 are to be satisfied during limited construction. For example, the organization roles and responsibilities as related to QA in the limited construction organization are not defined. Alternatively, the Plan does not reference the Contractor’s June 26, 2000, Limited Construction Authorization Request (LCAR) submittal, which discusses the methods and systems to be used during this phase of work. Reviewer Question 00-QA-13 was prepared to identify this concern, which is open. [See Appendix A for a full list of questions.]

The reviewers evaluated the extent to which the Plan identified the activities that are subject to the QAP. Although the Plan discusses the rationale for identifying SSCs within its scope, it does not adequately identify the activities that will be placed under the

QAP. For example, Section 1.3.1, “Classification of Items,” is devoted almost exclusively to classifying SSCs and does not adequately discuss the classification of activities or the process for identifying activities that are Important to Safety or could impact safety. Reviewer Question 00-QA-05 was prepared to identify this concern, which is open.

Reviewers also noted that Section 1.2.1 in the LCAR submittal discusses importance to safety from the standpoint of seismic category and performance category classifications, whereas Section 1.3.1 of the Plan discusses importance to safety in terms of safety design class and safety design significant classifications. Neither document has information to explain the relationship between these two sets of classification criteria. Reviewer Question 00-QA-07 was prepared to identify this concern, which is open.

2. The reviewers evaluated the Contractor’s provisions for describing the rationale and method for applying a graded approach. Section 1.3.2, “Graded Approach,” requires a graded approach and indicates that the rigor with which the quality program is applied to an activity is commensurate with the criteria identified in that section. These criteria are comparable to those listed in 10 CFR 830.120 and RL/REG-96-01, Rev. 1. Furthermore, the grading factors identified in Section 1.3.2 place adequate emphasis on importance to safety and quality. However, the Plan did not have sufficient detail to judge the adequacy of the Contractor’s grading process. For example, Section 1.3.2 does not specifically identify how the graded QA process will be implemented, nor does it adequately describe the Contractor’s rationale and method to determine the level of QA controls that will be applied. Reviewer Question 00-QA-08 was prepared to identify this concern, which is open.

The reviewers evaluated the Plan to confirm that the Contractor’s approach to grading is not used to obtain relief from the requirements of 10 CFR 830.120. Statements were added to the Plan, Section 1.3.1, and Section 7.3, “Dedicated Commercial Grade Items,” which make it unclear as to the extent to which the requirements of 10 CFR 830.120 are applied to “Dedicated Commercial Grade SSCs” within Quality Level (QL)-1 and QL-2 SSCs. Reviewer Questions 00-QA-06 and 00-QA-14 were prepared to identify this concern, which is open.

3. The reviewers evaluated the Contractor’s provisions for identifying the standards used to develop the Plan and specifying the use of 10 CFR 830.120 and QA-related standards. The wording in Section 1.3, “Requirements and Structure,” has been changed to where the Plan no longer clearly commits to 10 CFR 830.120. Reviewer Question 00-QA-03 was prepared to identify this concern, which is open.

4.2.3 Conclusion

On the basis of the evaluation described in this section, the reviewers concluded that the Contractor’s Plan does not adequately address the general requirements of 10 CFR 830.120 with respect to the following: (1) it does not adequately discuss how the criteria of 10 CFR 830.120 have been met for limited construction; (2) it does not adequately describe the graded approach

or how it is applied to the criteria of 10 CFR 830.120; and (3) it does not clearly commit to 10 CFR 830.120.

4.3 Specific QAP Requirements

4.3.1 Quality Assurance Program

4.3.1.1 Requirements

Three requirements in 10 CFR 830.120 pertain to Criterion 1, “Quality Assurance Program.” The requirements are provided below, followed by the specific attributes the reviewers used during their evaluation of the Plan:

1. “A written QAP shall be developed, implemented, and maintained.”
 - Expect the Plan to describe the Contractor’s management system, including the methods for managing, performing, and assessing the adequacy of work, such as work assigned to partners or parties outside the organization.
 - Evaluate the Contractor’s management system’s capability to achieve quality, with emphasis on the Contractor’s requirements for management qualification and participation.
 - Evaluate the Plan to verify that the method and resources for developing, implementing, and maintaining the document are adequate.
 - Confirm that the Contractor’s policies and requirements establishing the management system provide for management’s development of measures to ensure that all personnel, including management, understand and implement the management system.
 - Confirm that the Plan identifies a commitment to develop an implementation plan and evaluate the methods of management implementation and maintenance (e.g., periodic program reviews, demonstration of adequacy, provisions for changes, and method of approval of the document and future changes).
 - Identify the Contractor’s policies and requirements for assessing the adequacy of work.
2. “The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.”
 - Evaluate the adequacy of the Contractor’s organizational structure and provisions enabling personnel responsible for developing and implementing the QAP to have adequate lines of communication and sufficient influence to be effective.

- Confirm that the Plan provides information on the function of the various parts of the organization, their responsibilities, and how each supports the mission.
 - Verify that the Plan includes the following:
 - Organizational unit responsibilities
 - Level of authority for each tier of the organization
 - Interfaces among personnel managing, performing, and assessing the work
 - Authorities, responsibilities, and interfaces among multiple contractors or subcontractors.
 - Verify that the Plan describes communication among different organizations and between the organization and parties outside the organization.
 - Identify and evaluate a method for resolving inconsistencies among organizations and between organizations and parties.
3. “The QAP shall describe the management processes, including planning, scheduling, and resource consideration.”
- Identify and evaluate the adequacy of the Contractor’s policies and requirements that establish the management processes, including the following:
 - Identify and evaluate the provisions for the Contractor’s cost/schedule control system and the Management Information System.
 - Assess how the cost/schedule control system will be used, including the ability to track program progress and handle resource loading.
 - Assess how the Management Information System will be used and its adequacy to accommodate interfaces with all organizations and parties.

4.3.1.2 Evaluation

The reviewers evaluated the Contractor’s Plan using the requirements described in Section 4.3.1.1, above. The reviewers found that the Contractor’s Plan met Criterion 1. Evaluations for the attributes are discussed below (citations refer to the applicable section of the Plan):

1. The reviewers evaluated the provisions for describing the Contractor’s management system. In general, the Plan is organized and presented in a manner that describes the Contractor’s management system, including the Contractor’s methods for managing, performing, and assessing the adequacy of work.

The reviewers evaluated the Contractor's provisions for describing the capability of its management system to achieve quality, including management qualification and participation in the process. Management's participation in the QAP is described in the responsibilities portion of each section within the Plan.

The reviewers evaluated the Contractor's description of the method and resources for developing, implementing, and maintaining the Plan. Section 1.2, "Purpose and Scope," indicates that the project manager is responsible for providing adequate resources to plan, assess implementation, identify quality problems, and track corrective actions to completion. Section 9.3, "Management Assessments," requires management assessments to include evaluating the adequacy of resources and personnel provided to achieve and ensure quality.

The reviewers evaluated the Contractor's provisions for ensuring that all personnel, including management, understand and implement the management system. Section 2, "Personnel Training and Qualification," describes the measures to ensure that personnel are provided an adequate understanding of their responsibilities in implementing the management system.

The reviewers evaluated the Contractor's commitment to develop an implementation plan and provisions for maintaining the Plan. The implementation plan for the QAP is contained in Appendix A, "Implementation Plan for River Protection Project – Waste Treatment Plant Quality Assurance Program." Section 1.6, "Program Reviews," of the Plan requires an annual review of the QAP, project quality policies, and implementing project procedures for conformance with applicable regulatory and quality requirements. Section 1.6 also discusses the control of changes resulting from these reviews, including the process for reviewing and approving the revised QAP.

The reviewers evaluated the Contractor's provisions for assessing the adequacy of work. The Contractor's policies and requirements for assessing work adequacy are addressed in several places within the Plan, including Section 8, "Inspection and Acceptance Testing," Section 9, "Management Assessment," and Section 10, "Independent Assessment."

2. The reviewers evaluated the Contractor's provisions for describing the organizational structure and lines of communication. Section 1.3.5, "Organization," of the Plan describes the contractors who comprise the project team. In addition, the Plan shows the project management organization in Figure 1-3. Also, Section 1.4, "Responsibilities," of the Plan indicates that the QA manager has sufficient authority and organizational freedom to effectively communicate with other senior management positions and is sufficiently independent from cost and schedule considerations.

The reviewers evaluated the Contractor's provisions regarding the function of the various parts of the organization, their responsibilities, levels of authority, and how each supports the mission. This information is typically provided within each section of the Plan.

The reviewers evaluated the Contractor's description of interfaces. For example, Section 6.2.6, "Design Interfaces," of the Plan discusses the control of design interfaces, including coordination of the design effort among participating organizations both

internal and external to ensure integration of design and other technical requirements into the design documents. Section 6.2.6 also discusses the use of interface control documents for identifying lines of communication between interfacing organizations.

The reviewers evaluated the Contractor's provisions for resolving inconsistencies. Section 1.3.4, "Resolution of Quality Disputes," of the Plan provides a method for resolving differences of professional opinion involving QAP requirements. Section 6.3, "Responsibilities," of the Plan addresses the resolution of design and technical issues.

3. The reviewers evaluated the Contractor's description of how the Management Information System will be used. Section 1.5, "Management Processes," of the Plan describes the project management approach for providing project management oversight and integration of subcontractors performing engineering, procurement, and construction; regulatory and nuclear safety management; operations management; and interfaces with DOE and regulatory agencies. Section 1.5 also describes the project baseline, an integrated schedule developed by the Precedence Diagramming Method that is resource loaded to reflect increments of the project estimate. Section 1.5 also identifies the project procedures used to develop a cost and schedule plan, collect costs, forecast future requirements, and measure and report performance.

4.3.1.3 Conclusions

The reviewers determined that the description of the Contractor's QAP was acceptable. The reviewers found that the QAP adequately described the management system and that the descriptions of the Contractor's organization and management processes were also adequate.

4.3.2 Personnel Training and Qualification

4.3.2.1 Requirements

Two requirements in 10 CFR 830.120 pertain to Criterion 2, "Personnel Training and Qualification." The requirements are provided below, followed by specific attributes the reviewers used during their evaluation of the Plan:

1. "Personnel shall be trained and qualified to ensure they are capable of performing their assigned work."
 - Identify and evaluate the Contractor's policies, requirements, and methods that ensure personnel are trained and qualified to perform their work.
 - Confirm that the Contractor has adequately described its training and qualification processes, including the requirements, interfaces, training methods, and training responsibilities and duties of line and training organizations.
 - Consider the following questions:

- Are the personnel required to have an adequate understanding of the work they are to perform?
- Does the Contractor have provisions to certify the qualifications of personnel, and is the process description adequate?
- How will the Contractor identify the skills required to perform the work?
- Have personnel selection requirements been established for each position, including the minimum applicable requirements for education, experience, and physical condition?
- Does the Contractor's management specifically determine that personnel are suitably qualified to accomplish their assigned tasks?
- Consider the following when identifying and evaluating the Contractor's provisions for training:
 - Formal and informal training, such as on-the-job training
 - Training formats, including seminars and classroom instruction
 - Minimum requirements for each job task
 - Instructor qualifications and experience
 - Appropriate training materials and facilities
 - Methods for assessing personnel proficiency.
- Confirm that the Contractor's provisions for training address the following:
 - Workers attain knowledge of the correct processes and methods to accomplish assigned tasks.
 - Workers attain an understanding of the fundamentals of the work, the context within which the work is performed, and the reasons for any special work requirements.
 - Training goals, lesson plans, and other training materials are consistently developed, reviewed by subject matter experts, approved by management, and used to effectively deliver training.
 - Training materials are controlled to ensure that the latest approved versions are used.
 - Training effectiveness is constantly monitored.
 - Worker performance is evaluated to ensure that the training program conveys all required knowledge and skills.

- Workers are trained to new conditions if the work process is changed.
 - Feedback from personnel performance, former trainees, and supervisors is used to determine effectiveness of training, and the results of these evaluations are used as the basis for improving the training program.
 - Project-specific training is provided to impart the knowledge and skills required for the employee to successfully complete the project's mission.
 - Site-specific training is provided to convey the safety, security, and operations knowledge required to enter a specific site.
 - Institutional training is provided to convey general information about the organization's mission, vision, goals, and management system.
 - Instructors possess adequate technical knowledge, experience, and development and instructional skills.
 - Instructor training is based, in part, on the results of instructor evaluations and training on new methods and equipment.
 - Evaluate the Contractor's provisions regarding training plans to ensure the following are addressed:
 - Training plans are prepared for all personnel.
 - The content of initial training plans prepares personnel to perform the job.
 - The content of continuing training plans maintains and promotes progressive improvement in incumbent job performance.
 - The following are used to identify training plan content:
 - a. Current facility, site, or organization procedures
 - b. Technical and professional references
 - c. Past organization and industry experience.
2. "Personnel shall be provided continuous training to ensure that job proficiency is maintained."
- Identify and evaluate the Contractor's policies and requirements to establish continuing training.
 - Confirm that the workers are required to be trained to new conditions if the work process is changed.

- Consider the approach of using refresher courses to ensure personnel are trained in current procedures and on organizational processes, particularly if a condition adverse to quality may involve processes being performed incorrectly.
- Consider the following:
 - A periodic assessment of training needs
 - An assessment of process problems that may be solved by training
 - Instructor qualification and experience
 - Appropriate instruction materials and facilities
 - An assessment of personnel proficiency.

4.3.2.2 Evaluation

The reviewers evaluated the Contractor's Plan against 10 CFR 830.120, Criterion 2, using the requirements described in Section 4.3.2.1, above. The reviewers found that the Contractor's Plan met Criterion 2. Evaluations of the attributes are discussed below (citations refer to the applicable section of the Plan):

1. The reviewers evaluated the Contractor's provisions for ensuring that personnel are trained and qualified to perform their work. These provisions describe training and qualification processes and contain training methods, training responsibilities, and duties of the line and training organizations.

Section 2.2 also contains potentially conflicting information. The statement in the first paragraph, "Minimum education and experience shall be verified, or, when minimum education and experience cannot be verified, documented justification shall be provided for the personnel assignment," indicates that experience will be verified for all personnel. However, in the third paragraph, the statement, "Construction craft qualification by trade or labor agreement requirements is a basic premise for employment," indicates that the personnel supplied by the labor unions would be exempt from verification. Reviewer question 00-QA-10 was prepared to address this concern, which is open.

The reviewers evaluated the Contractor's provisions for developing training materials and ensuring that the materials are updated. This area was not addressed within the Plan.

The reviewers evaluated the Contractor's provisions for training to ensure that they address project-specific training and determined that these were adequately addressed in Section 2.2 of the Plan.

The reviewers evaluated the Contractor's provisions for training to ensure that they address site-specific training, including conveying the safety, security, and operations knowledge required to enter a specific site. Section 2.2 of the Plan addresses safety training but does not mention security and operations knowledge.

The reviewers evaluated the Contractor's provisions for training to ensure that they address institutional training, including conveying general information about the organization's mission, vision, goals, and management system. The Contractor did not address this type of training within the document.

The reviewers evaluated the Contractor's provisions for ensuring that instructors possess adequate technical knowledge, experience, and development and instructional skills, and this area was determined to be adequate. Section 2.2 states, "Formal training, when required, is provided by qualified instructors who possess the technical and instructional skills needed to accomplish instructional assignments in an effective manner."

2. The reviewers evaluated the Contractor's provisions for providing continuous training to ensure that job proficiency is maintained and found them to be adequate. Section 2.2, fourth paragraph, states, "Personnel reassigned or moved in the organization structure such that functions and responsibilities have changed significantly shall be retrained as necessary." However, Section 2.2 also discusses evaluation of worker performance and that the results of the evaluations would be incorporated into the training plans for future training. Also, the document does not describe how the evaluations feed into evaluations of the training program for effectiveness.

4.3.2.3 Conclusions

The reviewers determined the Contractor's personnel training and qualification processes described in the Plan to be acceptable, although certain attributes were not specifically addressed. The Contractor should further explain how it would verify the qualifications and experience for construction craft personnel (Question 00-QA-10).

4.3.3 Quality Improvement

4.3.3.1 Requirements

Two requirements in 10 CFR 830.120 pertain to Criterion 3, "Quality Improvement." The requirements are provided below, followed by specific attributes the reviewers used during their evaluation of the Plan:

1. "Processes to detect and prevent quality problems shall be established and implemented."
 - Identify and evaluate the Contractor's policies, requirements, and methods to detect and prevent quality problems; take prompt, effective, and complete corrective actions; and improve performance.
 - Consider the Contractor's management measures to do the following:
 - Document and communicate the policies to all levels of the organization and among organizations.

- Implement related practices, including those to improve worker awareness of the importance of quality.
 - Encourage participation of all workers in quality improvement.
 - Vest authority in workers to identify quality problems and initiate corrective actions.
 - Confirm that the Contractor’s documented policy for continuous improvement makes it clear that the responsibility for improvement rests with each individual and organizational element and cannot be delegated to a particular person or group within the organization.
 - Consider the Contractor’s use of methods like the Shewhart Cycle (also known as the Plan, Do, Check, Act, or PDCA cycle) to formalize the process of improving planning activities, procedures, processes, and designs.
2. “Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction shall include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items and processes needing improvement.”
- Identify and evaluate the Contractor’s policies for implementing procedures that identify, control, and correct quality deficiencies.
 - Consider the Contractor’s use of the following:
 - Methods for controlling items, services, or processes that do not meet requirements or specifications such as a classification system (e.g., accept, reject, repair, rework, use-as-is, or re-evaluate)
 - Methods for identifying and correcting items, services, or processes that do not meet requirements or specifications, including the tools of tracking, trending, and root cause analysis, to ensure that the underlying causes of quality problems are averted.

4.3.3.2 Evaluation

The reviewers evaluated the Contractor’s Plan using the requirements described in Section 4.3.3.1, above. The reviewers found that the Contractor’s Plan met Criterion 3. Evaluations of the attributes are discussed below (citations refer to the applicable section of the Plan):

1. The reviewers evaluated the Contractor's policies, requirements, and methods to detect and prevent quality problems; to take prompt, effective, and complete corrective actions; and to improve performance. The Contractor communicates quality improvement policies through the Plan and through initial indoctrination and training. The Contractor also commits to include quality improvement elements in work processes. In Section 3.2, "Requirements," the Contractor maintains an employee recommendation (suggestion) program. In addition, Section 3.2.1, "Control of Nonconforming Items, Services, and Processes," discusses that any employee may identify adverse conditions or deficiencies and submit them to management for disposition. While any employee may identify quality problems, the Plan does not discuss their responsibility for, or authority to, ensure corrective action is taken.

The reviewers confirmed that the Contractor's quality improvement process makes clear that the responsibility for improvements rests with each individual and organization and cannot be delegated. The Plan states that the responsibility for quality improvement belongs to each individual and organization and specifically extends this requirement to the nontechnical areas of planning, scheduling, and cost control. All project personnel are obligated by the Plan to identify nonconforming conditions or services and to identify opportunities to improve safety and quality and to reduce costs (Sections 3.2 and 3.3, "Responsibilities").

In Section 3.2.1, the Plan describes the specific management responsibilities and actions in prioritizing, tracking, and closing deficiencies. The Plan also commits the QA manager to prepare monthly reports that include "...areas of concern, opportunities for quality improvement, and ...adverse quality trends...." (Section 3.2.4, "Quality Assurance Program Status"). Specific quality improvement initiatives are not described, however, the description of the Contractor's processes to detect and prevent quality problems is adequate.

2. The reviewers evaluated the adequacy of the Plan in describing how quality deficiencies are identified, controlled, and corrected. The specifics of most parts of the Contractor's corrective action process are not provided in the Plan and could not be evaluated. However, the Contractor commits to have implementing documents/procedures in the areas of nonconformance reporting, corrective action, corrective action tracking, root cause analysis and Price-Anderson reporting (Appendix A, "Implementation Plan for River Protection Project – Waste Treatment Plant Quality Assurance Program," Table A-1). The description is therefore adequate.

The Contractor's description of its methods for controlling nonconforming items, services, and processes is adequate. In Section 3.2.1, the Contractor commits to identify, control, and disposition nonconforming items to prevent inadvertent use and provides acceptable detail on how such items are dispositioned.

The Contractor commits to a project-wide Corrective Action Management System (CAMS) to identify, track, analyze, resolve and trend deficiencies. According to Section 3.2.2, "Corrective Action," the CAMS requires root cause analysis for significant conditions adverse to quality. The Contractor also commits to a lessons learned system, including applying DOE's system.

4.3.3.3 Conclusions

The reviewers determined that the Contractor's quality improvement process and the methods, approaches, and systems used to implement the process as described in the Plan are acceptable.

4.3.4 Documents and Records

4.3.4.1 Requirements

Two requirements in 10 CFR 830.120 pertain to Criterion 4, "Documents and Records." The requirements are provided below, followed by specific attributes the reviewers used during their evaluation of the Plan:

1. "Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design."
 - Identify and evaluate the Contractor's policies and requirements for document control and the implementation of a document control process.
 - Confirm that the Contractor commits to identify any documents that must be controlled.
 - Evaluate the Contractor's measures to ensure all elements of the organization establish document control procedures.
 - Identify and evaluate the Contractor's requirements and standards for document preparation, review, approval, use, access, and revision.
 - Evaluate the Contractor's approaches for controlling distribution, identifying recipients, identifying unique revisions and copies, and establishing required actions when documents are revised or canceled consistent with the results of the graded approach.
 - Identify and evaluate the Contractor's measures to ensure reviewers are qualified based on subject matter expertise.
 - Evaluate the Contractor's document control provisions against the requirements for configuration management in the top-level safety standards and principles stipulated by DOE.
2. "Records shall be specified, prepared, reviewed, approved, and maintained."
 - Identify and evaluate the Contractor's policies and requirements for specifying, preparing, reviewing, approving, and maintaining records.

- Confirm that the Contractor commits to identify any records that must be generated.
- Evaluate the Contractor's description of how records are determined, the process of preparation, the method of review, the process of approval, and the system for maintenance in light of a graded approach.
- Evaluate the Contractor's record control system considering the requirements for retaining, protecting, preserving, changing, tracing, accounting for, and retrieving records.
- Assess the adequacy of the Contractor's requirements to preserve the integrity of the records while they are in storage to protect them from damage, loss, and deterioration.
- Confirm that the Contractor's provisions for controlling records address the hardware and software required to maintain, control, and access the records to ensure they remain usable (e.g., for records that require electronic processing control, such as information recorded on magnetic media and optical disks).
- Confirm that the Contractor's provisions are adequate to ensure that its records are sufficient to support technical and regulatory decisions.

4.3.4.2 Evaluation

The reviewers evaluated the Contractor's Plan using the requirements described in Section 4.3.4.1, above. The reviewers found that the Contractor's Plan met Criterion 4. Evaluations of the attributes are discussed below (citations refer to the applicable section of the Plan):

1. The reviewers evaluated the Contractor's provisions for preparing, reviewing, approving, issuing, using and revising documents and found them to be adequate. The Contractor's approach to document control is discussed in Sections 4.2.1, "Documents," with the exception of changes to documents, which is discussed in Section 4.2.2, "Records." The Contractor's provisions for requiring the reviewers of documents to be qualified subject matter experts are discussed in Section 4.2.1. The descriptions provided in these sections of the Plan meet the attributes of Section 4.3.4.1, part 1.
2. The reviewers evaluated the Contractor's provisions for specifying, preparing, reviewing, approving, and maintaining records and found them to be adequate. The Contractor's approach to record management is discussed in Section 4.2.2. These provisions included measures to retain, protect, preserve, correct, and retrieve records. The Contractor commits that records retention (storage) and turnover "shall ...meet the requirements of ASME NQA-1 Supplement 17S-1, "Supplementary Requirements for Quality Assurance Records." Provisions are also included for records that require electronic processing control. The descriptions provided in these sections of the Plan meet the attributes of Section 4.3.4.1, part 2.

4.3.4.3 Conclusions

The reviewers determined that the Contractor's document control and records management processes described in the Plan - including methods, systems, and approaches to implement the processes - are acceptable.

4.3.5 Work Processes

4.3.5.1 Requirements

Four requirements in 10 CFR 830.120 pertain to Criterion 5, "Work Processes." The requirements are listed below, followed by specific attributes the reviewers used during their evaluation of the Plan:

1. "Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means." **[Work Performance]**
 - Identify and evaluate the Contractor's policies and requirements for such management controls as the following:
 - Providing criteria for acceptable work performance, planning, and designing work processes
 - Ensuring qualified personnel accomplish the work
 - Ensuring that personnel take responsibility for the quality of their own work and that they follow prescribed standards, procedures, or instructions.
 - Verify that documents expressing management controls meet the following:
 - Clearly identify authorities, responsibilities, and interfaces
 - Are readily accessible to and usable by the worker
 - Address work process elements such as methods to prevent use of incorrect or defective items
 - Include any requirements for special processes that are highly dependent on the control of the process or the skill of the operator and for which the quality of the product cannot be readily determined by inspection or test.
 - Evaluate the Plan's description of each important element of each work process (i.e., people, equipment, environmental conditions, supply, management, support, resources, and requirements) based on the results of the graded approach.

2. “Items shall be identified and controlled to ensure their proper use.” **[Item Identification and Control]**
 - Identify the Contractor’s policies and requirements for identifying and controlling items.
 - Expect the Contractor’s Plan to describe use of a system to inventory items and a method to track and control items and accompanying documentation, depending on importance.
 - Confirm the Contractor’s management’s commitment to a system that is used to identify and control items and that is readily usable by workers.
 - Identify the Contractor’s policies and requirements ensuring that the personnel take responsibility for properly using the items.
 - Expect the Contractor’s policies and procedures to address the following: one-of-a-kind items, items specific to a particular craft, and common items that may be misused.

3. “Items shall be maintained to prevent their damage, loss, or deterioration.” **[Item Protection]**
 - Identify and evaluate the Contractor’s policies and requirements for a process or procedure that ensures item maintenance or special care according to their importance (graded approach).
 - Evaluate the Contractor’s measures in the maintenance management program to promote worker safety and environmental protection and to monitor item condition.
 - Consider the following attributes: maintenance requirements, an item control process, maintenance schedules, personnel or organizations identified for maintenance, assignment of authority and resources to meet requirements, handling and storage requirements to prevent damage, a method of measuring deterioration, and establishment of metrics for determining deterioration.

4. “Equipment used for process monitoring or data collection shall be calibrated and maintained.” **[Equipment Control]**
 - Identify and evaluate the Contractor’s policies and requirements for identifying, controlling, and maintaining equipment used for monitoring processes or collecting process or other data.
 - Identify and evaluate the Contractor’s requirements for a formal, documented, calibration program.

4.3.5.2 Evaluation

The reviewers evaluated the Contractor's Plan using the requirements described in Section 4.3.5.1, above. The Plan subdivides the requirements associated with this portion of 10 CFR 830.120 differently than the rule does. The table below identifies the sections of the Contractor's Plan and the associated 10 CFR 830.120 requirements, identified in Section 4.3.5.1 utilized for the evaluation.

Contractor Plan Section	Applicable Requirements
5.3.1 – Project Management and Planning	Work Performance
5.3.2 – Procedures and Instructions	Work Performance
5.3.3 – Identification and Control of Items	Item Identification and Control
5.3.4 – Control of Special Processes	Work Performance
5.3.5 – Control of Measuring and Test Equipment	Equipment Control
5.3.6 – Handling, Storage, and Shipping	Item Protection
5.3.7 - Construction	Work Performance
5.3.8 – Sample Control	Item Identification and Control

Section 5.2 incorrectly lists Document Control as a set of activities controlled by Section 5. Section 4 of the Plan defines the requirements for Document Control. Evaluations of the attributes are discussed below (citations refer to the applicable section of the Plan).

1. Section 5.3.1, "Project Management and Planning" addresses general planning and work control. The section refers to the Project Management Plan, stating that the plan describes the overall approach and objectives for the Contractor's management of project work. Therefore, the details of those processes are deferred to the Project Management Plan and supporting procedures, which are outside the scope of this review. The Plan defines the general scope of project work, identifies a general requirement for functional managers to perform work planning, and defines a general requirement for developing procedures to control special processes.

In the Plan, Table A-1, "Quality Assurance Program Implementation Matrix," identifies specific implementing documents and procedures to be developed for each of the 10 criteria of 10 CFR 830.120. However, no procedure is listed for the work planning requirements of 10 CFR 830.120. Implementation of those requirements may be provided in the Project Management Plan or one of its supporting procedures. A question (00-QA-12) was submitted to the Contractor to identify this concern, which is open. The items not addressed specifically in the Plan are as follows:

- Ensuring qualified personnel accomplish the work
- Ensuring that personnel take responsibility for the quality of their own work and that they follow prescribed standards, procedures, or instructions.

With the exceptions noted above, Section 5.3.1 of the Plan complies with the requirements of 10 CFR 830.120.

Section 5.3.2, “Procedures and Instructions,” defines requirements for preparing and using procedures and instructions. The section specifies management approval and control of the documents that control work. Section 5.3.2 complies with the requirements of 10 CFR 830.120.

Section 5.3.4, “Control of Special Processes,” addresses an important activity during construction is the control of special processes. Special processes are work processes, the results of which depend on the control of the process or the skill of the worker, or both. In addition, for special processes, the quality of the completed work cannot easily be verified after their completion and thus require additional QA/QC controls. Traditionally, special processes include activities such as welding, heat-treating, and chemical cleaning. For the Contractor’s work scope, special processes are expanded to include scientific investigations and work unique to processing high level waste. The criteria of 10 CFR 830.120 do not include requirements for special processes specifically, although they flow out of work processes. The Plan adequately defines the basic requirements for control of special processes with Table A-1 identifying supporting procedures that will be developed. Section 5.3.4 complies with the requirements of 10 CFR 830.120.

Section 5.3.7, “Construction,” specifies requirements for controlling activities related to construction. The requirements specified by Section 5.3.7 comply with the applicable portions of 10 CFR 830.120.

2. Requirements for identifying and controlling items are addressed by Section 5.3.3, “Identification and Control of Items,” of the Plan. The section addresses identification of items, identification methods, traceability, control of items with limited shelf life, and storage of material. The following attributes were not specifically addressed:
 - The system to inventory items and a method to track and control items and accompanying documentation, depending on importance
 - The system that is used to identify and control items and that is readily usable by workers
 - Policies and requirements ensuring that personnel take responsibility for properly using the items
 - Policies and procedures addressing one-of-a-kind items, items specific to a particular craft, and common items that may be misused.

These items should be addressed in procedures or other documents subtier to the Plan. Section 5.3.3 complies with the requirements of 10 CFR 830.120.

Section 5.3.8, “Sample Control,” provides for the identification and control of samples. Other documents provide details of the control of samples. Sample Control is a special type of Item Identification and Control. The section complies with the applicable portions of 10 CFR 830.120.

3. Section 5.3.6, “Handling, Storage, and Shipping,” addresses the requirements for controlling items to prevent damage or loss, as well as to minimize deterioration. The requirement related to maintenance was not fully addressed. However, because of the Plan’s level in the document hierarchy and because maintenance activities would not be expected to be ongoing under the LCAR, the omission of this requirement is not considered a deficiency. The specific attributes not addressed were:
 - Policies and requirements for a process or procedure that ensures item maintenance or special care according to their importance (graded approach)
 - Measures in the maintenance management program to promote worker safety and environmental protection and to monitor item conditions.
4. Section 5.3.5, “Control of Measuring & Test Equipment,” defines controls for ensuring that equipment used for monitoring or controlling processes or collecting data are properly controlled, calibrated, and maintained. The section defines a set of controls that are to be applied to M&TE. The section complies with the requirements of 10 CFR 830.120.

4.3.5.3 Conclusions

The reviewers determined that the Contractor’s work processes are acceptable, except for the concern discussed under project management and planning (00-QA-12).

4.3.6 Design

4.3.6.1 Requirements

Five requirements in 10 CFR 830.120 pertain to Criterion 6, “Design.” The requirements are provided below, followed by specific attributes the reviewers used during their evaluation of the Plan:

1. “Items and processes shall be designed using sound engineering/scientific principles and appropriate standards.”
 - Identify and evaluate the Contractor’s policies and requirements for using sound engineering/scientific principles.
 - Consider the Contractor’s use of the following:
 - Accepted design practices

- Valid analytical methods
 - Tools and data
 - Proven technology or measures to demonstrate adequacy of new technology
 - Formal design processes that ensure quality.
- Confirm that the Contractor's provisions for design require design inputs that are technically correct and complete.
 - Confirm that the Contractor's measures address QA methods that are unique to analysis.
 - Confirm that the Contractor's provisions for design require the design process to translate design input into design output documents that are technically correct and meet the end users' requirements.
 - Verify that aspects critical to the safety of designed SSCs are required to be identified during the design phase.
 - Confirm that the Contractor's provisions for design require the computer software used to originate the design or verify design solutions during the design process to be validated or the status of code validation to be identified and documented before it is used.
 - Verify that the Contractor has established measures to preclude the use of unverified design data and to ensure that appropriate verification or qualification testing is completed before design data are used in subsequent activities, consistent with the results of the graded approach.
 - Identify and evaluate the Contractor's requirements for identifying and using suitable standards appropriate to the design product.
2. "Design work, including changes, shall incorporate applicable requirements and design bases."
- Identify and evaluate the Contractor's policies and requirements for a formal process, including systems engineering, to properly establish and accurately incorporate requirements and design bases into the design and design changes.
 - Confirm that the Contractor's provisions for design require the completed design to be recorded in design output documents such as drawings, specifications, test/inspection plans, maintenance requirements, and reports.

- Confirm that as-built drawings and shop drawings are required to be maintained after production or construction to show actual configuration.
 - Verify that design changes, including those made during fabrication or construction, subsequent modifications, and any nonconforming items will be subject to design standards and controls consistent with those applied to the original design.
 - Verify that temporary modifications are required to receive the same levels of control as the designs of permanent modifications.
 - Identify requirements for configuration management and control to ensure that design documents and records are appropriately generated, controlled, and retained.
 - Identify and evaluate the Contractor's requirements for a process to identify SSCs Important to Safety, consistent with the graded approach, and establish the life expectancy of the SSC.
 - Identify requirements for design documents to be usable by all end users.
3. "Design interfaces shall be identified and controlled."
- Identify and evaluate the Contractor's policies and requirements for determining design interfaces among interacting disciplines or multiple contractors, both technical and administrative.
 - Identify and evaluate the Contractor's requirements for an interface control system that avoids or identifies and corrects conflicts.
 - Verify that the administrative interface process clearly indicates responsibilities for design output document activities, including as built, mark-up, and updating during project construction and production phases, media use and transmission, document control, and records management.
4. "The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work."
- Identify and evaluate the Contractor's policy and requirements to verify or validate design products consistent with the results of the graded approach.
 - Confirm that the Contractor's provisions for design require the Contractor to verify that design output documents meet design input requirements and that any deviations are approved and documented.
 - Confirm that technically qualified personnel, separate from those performing the design, will verify the design.

5. “Verification and validation work shall be completed before approval and implementation of the design.”
 - Identify and evaluate the Contractor’s policies and requirements to verify and validate the design before other organizations use it.

4.3.6.2 Evaluation

The reviewers evaluated the Contractor’s Plan against Criterion 6 of 10 CFR 830.120, using the requirements described in Section 4.3.6.1, above. The reviewers found that, for the most part, the Contractor’s Plan met Criterion 6. Section 6, “Design,” in the Plan defines the Contractor’s controls to be applied to design activities. The section specifies that implementing procedures will be developed with that reflected in Table A-1, “Quality Assurance Program Implementation Matrix.” Evaluations of the attributes are discussed below (citations refer to the applicable section of the Plan).

1. The reviewers evaluated the Contractor’s commitment to using sound engineering and scientific principles and full compliance with the applicable requirements. Section 6.2.1, “Design Principles,” provided an adequate description of the Contractor’s commitment in this area.
2. The reviewers evaluated the Contractor’s provisions for incorporating applicable requirements and design bases into design work. Section 6.2.4, “Design Input,” specifies that design inputs shall be technically correct and complete. Essential design inputs are to be identified, reviewed, and approved by the responsible engineering group. The control of the design inputs, including the functional requirements and the design criteria, is also ensured by the Contractor’s Configuration Management Program, as specified in Section 6.2.5, “Configuration Management.”
3. The reviewers evaluated the Contractor’s commitment to identifying and controlling design interfaces. The Plan specifies such identification and control in Section 6.2.6, “Design Interfaces.”
4. The reviewers evaluated the Contractor’s commitment to verifying or validating the adequacy of design products by individuals or groups other than those who performed the work. The checking of design products is addressed by Section 6.2.9, “Design Checking”; verification is addressed in Section 6.2.10, “Design Verification”; and both, including independent verification, are addressed in Section 6.2.2, “Design Process.”
5. The reviewers evaluated the Contractor’s commitment to completing verification and validation work before the design is approved and implemented. Section 6.2.10 of the Plan specifies that verification be performed before the design is released.

4.3.6.3 Conclusions

The reviewers determined that the Contractor's design provisions, as described in the Plan, are acceptable and in compliance with 10 CFR 830.120.

4.3.7 Procurement

4.3.7.1 Requirements

Three requirements in 10 CFR 830.120 pertain to Criterion 7, "Procurement." The requirements are provided below, followed by specific attributes the reviewers used during their evaluation of the Plan:

1. "Procured items and services shall meet established requirements and perform as specified."
 - Identify and evaluate the Contractor's policies and requirements for planning and controlling the procurement process consistent with the results of the graded approach.
 - Evaluate the Contractor's provisions for procurement documents to ensure that the following are addressed:
 - Procurement documents clearly state test/inspection requirements and acceptance criteria for purchased items and services.
 - Procurement documents include any specifications, standards, and other documents referred to by the design documents.
 - Critical parameters and requirements such as submittals, product-related documentation, nonconformance requirements, administrative documentation, personnel or materials qualification, tests, inspections, and reviews are specified as line items.
 - Confirm that the Contractor's provisions require supplier-generated documents to be adapted through the procurement system and to be controlled and processed according to the provisions of Criterion 4, "Documents and Records."
 - Identify and evaluate the Contractor's policies and requirements for documenting and controlling nonconforming items or services until compliance with the technical requirements is demonstrated and for documenting, controlling, reviewing, and approving acceptable deviations from requirements.
 - Evaluate the Contractor's provisions for inspections to ensure the following are addressed:

- The procurement system includes provisions for inspections.
 - Requirements for inspections are obtained from design documents.
 - Inspections are adequate to ensure conformance with purchase requirements, including verifying that the supplier has provided specified documentation.
 - The inspection verifies that items were not damaged during shipment.
 - The procurement system includes provisions for conducting testing activities that may be required during the procurement process.
2. “Prospective suppliers shall be evaluated and selected on the basis of specified criteria.”
- Identify the Contractor’s policies and requirements to ensure suppliers are qualified to provide required items or services.
 - Evaluate the Contractor’s provisions for supplier qualification to ensure the following are addressed:
 - Required qualified suppliers are identified early in the design and procurement process.
 - The prospective suppliers are evaluated to verify their capability to meet performance and schedule requirements.
 - The qualified suppliers are evaluated periodically to confirm their continuing capabilities.
3. “Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.”
- Identify and evaluate the Contractor’s policies and requirements to establish a process to evaluate a supplier’s continued capability to provide acceptable items and services.
 - Verify that the required supplier monitoring is performed during the procurement process to ensure acceptable items or services and schedule requirements are being met. The extent and number of reviews should be based on the results of the graded approach. Enhanced reviews may be stimulated by receipt of nonconforming items from the supplier.

4.3.7.2 Evaluation

The reviewers evaluated the Contractor's Plan against Criterion 7 of 10 CFR 830.120, using the requirements described in Section 4.3.7.1, above. The reviewers found that the Contractor's Plan met Criterion 7. Section 7, "Procurement," in the Plan defines the Contractor's QAP controls to be applied to procurement activities. The section specifies that implementing procedures will be developed with that reflected in the Plan's Table A-1, "Quality Assurance Program Implementation Matrix." Evaluations of the attributes are discussed below (citations refer to the applicable section of the Plan).

1. The reviewers evaluated the Contractor's provisions for procured items and services to meet established requirements and perform as specified. Section 7.2.1, "Technical Requirements," adequately addresses technical requirements; Section 7.2.2, "Procurement Documents," adequately addresses procurement documents.
2. The reviewers evaluated the Contractor's provisions for evaluating and selecting prospective suppliers on the basis of specified criteria. Section 7.2.3, "Supplier Qualifications," adequately addresses supplier qualifications.
3. The reviewers evaluated the Contractor's provisions for establishing and implementing processes to ensure that approved suppliers continue to provide acceptable items and services. Section 7.2.4, "Supplier Monitoring," adequately addresses supplier monitoring.

Attributes not addressed in Section 7 of the plan include the following. These items would normally be addressed in implementing documents, and are therefore not considered a deficiency:

- End-user requirements should include supplier documentation, handling, packaging, shipping, or storage requirements.
- The Contractor has policies and requirements for documenting and controlling nonconforming items or services until compliance with the technical requirements is demonstrated and for documenting, controlling, reviewing, and approving acceptable deviations from requirements.

4.3.7.3 Conclusion

The reviewers determined that the Contractor's procurement process, as described in the Plan, is acceptable and in compliance with 10 CFR 830.120.

4.3.8 Inspection and Acceptance Testing

4.3.8.1 Requirements

Two requirements in 10 CFR 830.120 pertain to Criterion 8, “Inspection and Acceptance Testing.” The requirements are provided below, followed by specific attributes the reviewers used during their evaluation of the Plan:

1. “Inspection and testing of specified items, services, and processes shall be conducted using established acceptance and performance criteria.”
 - Identify and evaluate the Contractor’s policies and requirements to establish inspection and testing to verify the acceptability of physical characteristics and functions of SSCs consistent with the results of the graded approach.
 - Evaluate the Contractor’s measures to ensure that inspection and testing activities are adequately planned, controlled, and documented.
 - Identify the Contractor’s measures to ensure that SSCs requiring inspection and testing are identified early in the design phase and that acceptance parameters and other requirements such as inspection and test equipment or qualified inspection and test personnel are specified in design documentation (e.g., provisions to control disposition of SSCs that do not conform, including tracking, repair, replacement, re-testing, and re-evaluation to specified criteria and disposal).
 - Confirm that the Contractor’s provisions for inspection and testing address the following:
 - The inspection and testing process identifies the status of SSCs that need to be examined to ensure that failed or untested SSCs are not used.
 - Re-inspection and re-testing for previously failed SSCs are controlled.
 - Review and documentation are provided for changed inspection and test parameters.
 - Identify measures to ensure that equipment used for inspections is appropriate and that personnel performing inspections and test are trained and qualified in the test procedures and equipment to be used and are certified in the appropriate discipline as necessary (e.g., nondestructive examination qualifications).
 - Evaluate the Contractor’s provisions for ensuring that inspection and test activities are performed by persons other than those who perform or directly supervise the work being examined and that test personnel have the freedom of access and communication to report inspection/test results.

- Identify measures to ensure that inspection and test documentation contains provisions for at least the following:
 - Identification of characteristics to be examined
 - Required qualifications of individuals who perform the examination
 - Description of the examination methods, including equipment and calibration requirements
 - Acceptance and rejection criteria
 - Required safety measures
 - Actions taken concerning any deviations noted.
- Identify measures to ensure that inspection and test results are evaluated and verified by authorized personnel to document that all requirements have been satisfied.
- Evaluate the Contractor's provisions to ensure that records of inspection and test activities, at a minimum, identify the following:
 - Item tested
 - Date of test
 - Tester or data recorder
 - Observations
 - Results and acceptability
 - Actions taken concerning any deviations noted.

2. "Equipment used for inspections and tests shall be calibrated and maintained."

- Identify the Contractor's policies and requirements to establish a formal, documented, calibration program consistent with the results of the graded approach. Calibration standards should be traceable to a recognized authority, such as the National Institute of Standards and Technology, which gives the basis for the calibration.
- Evaluate the Contractor's provisions for calibrating equipment and instruments used to establish the acceptance of items, processes, procedures or services; corrective actions where out-of-calibration conditions occur; and the use of qualified personnel performing calibrations.
- Identify measures to ensure that M&TE used to verify conformance to design requirements are the proper type, range, and accuracy and are uniquely identified and traceable to their calibration data.

- Evaluate the measures to ensure that adequate procedures for testing, re-testing, adjusting, and re-calibration of M&TE are maintained and documented by organizations performing inspection and testing functions.

4.3.8.2 Evaluation

The reviewers evaluated the Contractor's Plan against Criterion 8 of 10 CFR 830.120, using the requirements described in Section 4.3.8.1, above. The reviewers found that the Contractor's Plan met Criterion 8. Section 8, "Inspection and Acceptance Testing," of the Plan defines the Contractor's controls to be applied to inspection and testing activities. Table A-1, "Quality Assurance Program Implementation Matrix," in the Plan identifies implementing procedures that will be developed. Evaluations of the attributes are discussed below (citations refer to the applicable section of the Plan).

1. The reviewers evaluated the Contractor's provisions for ensuring that the inspection and testing of specified items, services, and processes will be conducted using established acceptance and performance criteria. Section 8.2.1 addresses Inspection activities, including inspection procedures, inspection methods, receiving inspection, and final inspection. Section 8.2.1.3 addresses in-process measurement, inspection, and verification, while Section 8.2.1.4 addresses qualification and certification of inspection personnel.

Test control is addressed in Section 8.2.2. The Plan addresses test procedures in Section 8.2.2.2 and test results in Section 8.2.2.3.

2. The reviewers evaluated the Contractor's provisions for calibrating and maintaining equipment used for inspections and tests. The Plan commits to performing inspections and tests according to DOE/RL-96-0006, Section 4.3.5.1. Section 8.2.3, "Control of Measuring and Testing Equipment," addresses the calibration control of M&TE, supplementing Section 5.3.5, "Control of Measuring and Testing Equipment."

All of the characteristics and attributes described in Section 4.3.8.1, above, are addressed, with the exception of any discussion of the use of a graded approach to inspection and testing. Reviewer Question 00-QA-08 was prepared to identify this concern regarding the application of the graded approach (see Section 4.2.2 of this report), which is open.

4.3.8.3 Conclusion

The reviewers determined that the Contractor's inspection and testing provisions, as described in the Plan, is acceptable and in compliance with 10 CFR 830.120.

4.3.9 Management Assessment

4.3.9.1 Requirements

Two requirements in 10 CFR 830.120 pertain to Criterion 9, “Management Assessment.” The requirements are provided below, followed by specific attributes the reviewers used during their evaluation of the Plan:

1. “Management shall assess their management processes.”
 - Identify and evaluate the Contractor’s policies and requirements for assessing management processes.
 - Verify that the Contractor’s provisions for management assessment require that managers at every level periodically assess the performance of their organization and that managers retain overall responsibility for management assessments.
 - Confirm that the Plan includes measures to establish organizational goals and objectives and the conduct of periodic assessments that evaluate the effectiveness of the entire integrated management system to focus on achieving organizational goals.
 - Verify that the Contractor’s provisions for management assessment do the following:
 - Evaluate processes such as strategic planning, organizational interfaces, cost control, use of performance indicators, staff training and qualifications, and supervisory oversight and support.
 - Evaluate conditions such as employee knowledge, motivation, and morale; worker trust and communication; worker dedication to creativity and improvement; and adequacy of human and material resources.
 - Include work observations such as upward evaluations, worker interviews, reviews of documentation, and conduct of drills or exercises.
2. “Problems that hinder the organization from achieving its objectives shall be identified and corrected.”
 - Identify the Contractor’s policies and procedures for identifying and correcting problems that hinder the organization from achieving its objectives, including corrective actions.
 - Evaluate the Contractor’s measures to use the information acquired during assessments combined with other internal and external information to identify problems and to develop input to a continuous improvement process.

- Evaluate the Contractor's methods for improving processes and eliminating the barriers to achieving strategic goals and objectives.

4.3.9.2 Evaluation

The reviewers evaluated the Contractor's Plan against Criterion 9 of 10 CFR 830.120, using the requirements described in Section 4.3.9.1, above. The reviewers found that the Contractor's Plan met Criterion 9. Evaluations of the attributes are discussed below (citations refer to the applicable section of the Plan):

1. The reviewers evaluated the provisions for identifying who is responsible to establish, monitor, and improve the overall process for conducting management assessments within the project and determined this was an area that needed further clarification. Requirements in Section 9.3, "Management Assessments," identify that "managers of all levels will assess the performance of their organization" and in Section 9.4, "Responsibilities," requires that line and functional managers be responsible for scheduling, performing, and documenting management assessments. Section 9.4 identifies that the project manager is required to annually review the overall effectiveness of the management assessments. However, the Plan does not clearly indicate who is responsible for establishing the management assessment process and overseeing the operation for effectiveness and continuous improvement. Reviewer Question 00-QA-11 was prepared to identify this concern, which is open.

The reviewers evaluated the provisions to require all managers of all levels to periodically assess the performance of their organization. This is adequately addressed in Sections 9.3 and 9.4. The responsibility for implementing the corrective actions is addressed in Section 3.2.1, "Control of Nonconforming Items, Services, and Processes," paragraph 6.

The reviewers evaluated the provisions to conduct periodic assessments that evaluate the effectiveness of the management system to focus on achieving organizational goals. The Project Quality Policy states, "It is the Project policy to provide goods and services, which fully satisfy and comply with customers and regulator's requirements. To achieve this objective...." In the first sentence satisfying requirements is described as a policy, and in the second sentence it is described as an objective. This indicates some confusion on the distinction between the policy, goals, objectives, and performance measures. However, because the Contractor commits to focus management assessments on the issues that affect performance and enable the organization to meet project needs, customer requirements, and expectations, overall the Contractor's commitment is acceptable.

The reviewers evaluated the provisions for evaluating processes and conditions using a variety of methods such as employee interviews, document reviews, and conduct of drills (readiness reviews) and found this to be acceptably identified in Section 9.3.

The reviewers evaluated the provisions to use evaluation results in the continuous improvement process. This is adequately addressed by requirements in Section 3.0, “Quality Improvement.”

2. The reviewers evaluated the Contractor’s provisions for using internal management assessment results to identify problems that would hinder the achievement of objectives. This is adequately addressed in Section 3.0, “Quality Improvement,” and Section 9.3, “Management Assessment,” which discuss the use of internal and external information for continuous improvement.

The reviewers evaluated the Contractor’s provision for using internal and external assessment results to drive improvement. This is adequately identified in Section 9.3, paragraph 8.

The reviewers evaluated the Contractor’s provisions for looking at resources (tools and personnel) to drive improvement. This is adequately identified in Section 9.3, paragraph 7.

The reviewers evaluated the Contractor’s commitment to use a tracking system to ensure issues are addressed. This is adequately addressed in Section 3.0, where the Contractor commits to a project-wide CAMS to identify, track, analyze, resolve, and trend deficiencies.

The reviewers evaluated the Contractor’s commitment for prioritizing corrective actions. This is adequately addressed in Section 3.2.1, “Control of Nonconforming Items, Services, and Processes,” with the specification of management responsibilities and action to prioritize, track, and close deficiencies.

The reviewers evaluated the Contractor’s commitment for looking for trends that may develop from a multitude of singular issues. This is adequately addressed in Section 3.2.4, “Quality Assurance Program Status,” where the QA Manager is responsible to prepare a monthly report that includes “areas of concern, opportunities for quality improvement, and ... adverse quality trends.”

4.3.9.3 Conclusion

The reviewers determined that the Contractor’s provisions for management assessment are acceptable.

4.3.10 Independent Assessment

4.3.10.1 Requirements

Three requirements in 10 CFR 830.120 pertain to Criterion 10, “Independent Assessment.” The requirements are provided below, followed by specific attributes the reviewers used during their evaluation of the Plan:

1. “Independent assessments shall be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.”
 - Evaluate the Contractor’s specified criteria grounded in a performance-based approach with emphasis on results and with compliance viewed as the baseline.
 - Evaluate the Contractor’s planning of assessments and the selection of activities for assessment, such as design, that are most directly related to final objectives and its emphasis on safety and product quality.
 - Evaluate the Contractor’s selection of types of independent assessments, such as inspections, peer and technical reviews, audits, surveillances, or combinations thereof; the frequency of independent assessments in light of activities being assessed; and their status, complexity, and importance.
 - Evaluate the effectiveness of the Contractor’s approach to measure item and service quality, to measure adequacy of work performance, and to promote improvement.
 - Confirm that assessment results are documented, presented to the organization that was assessed, and provided to the appropriate levels of management for review. Identify the strengths and weaknesses affecting the quality of process outputs so that meaningful action can be taken to improve quality.
 - Confirm that the independent assessment process includes verification of the adequacy of corrective actions, including actions identified to prevent recurrence or to otherwise improve performance.
 - Verify that identified action items are required to be tracked for resolution and evaluated to determine whether similar deficiencies exist elsewhere.
 - Verify that lessons learned from the assessment process are required to be communicated to other organizations with similar activities or concerns.
 - Confirm that areas of poor or questionable performance are required to receive increased attention. Independent assessments that verify good performance in some or all areas of an organization could reduce the frequency and depth of future assessments.
2. “The group performing independent assessments shall have sufficient authority and freedom from the line to carry out its responsibilities.”
 - Confirm that the assessing organization is required to report to a sufficiently high level in the overall organization to ensure organizational independence and access to appropriate levels of authority.

- Confirm that the group would have no direct responsibilities or dependencies in the areas they are assessing.
 - Confirm that the group's role includes assisting those being assessed to improve quality.
3. “Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.”
- Identify the Contractor’s policies and requirements for ensuring personnel conducting independent assessments are technically qualified and knowledgeable.
 - Confirm that the QAP requires assessment personnel have the necessary technical knowledge to accurately observe and evaluate activities being assessed.
 - Confirm that the QAP prohibits assessment personnel from reinterpreting or redefining the requirements specified in approved programs.
 - Confirm that the QAP includes measures to establish appropriate qualifications for the assessments and to select appropriate personnel for conducting the assessment.

4.3.10.2 Evaluation

The reviewers evaluated the Contractor’s Plan against Criterion 10 of 10 CFR 830.120, using the requirements described in Section 4.3.10.1, above. The reviewers found that the Contractor’s Plan met Criterion 10. Evaluations of the attributes are discussed below (citations refer to the applicable section of the Plan):

1. The reviewers evaluated the Contractor’s commitment for evaluating the Plan’s implementation. Section 3.2, “Requirements,” identifies many of the mechanisms to ensure the implementation of the Plan and to provide input for continuous improvement. These mechanisms, in combination with the requirement for management assessments in Section 9.4, “Responsibilities,” create a broad base for collecting information on implementing the Plan and adequately address this commitment. Section 10.2.1, “Independent Assessment,” states, “Assessments are performed in all areas where the requirements of the QAP apply.”

The reviewers evaluated the Contractor’s provisions to provide results of independent assessment into the quality improvement process(es) and found them to be adequately addressed in Section 3.2.1, “Control of Nonconforming Items, Services, and Processes.” Also, Section 10.2.5, “Management Responses and Actions,” states that management should include “...deficiency tracking and monitoring using the corrective action management systems database.”

The reviewers evaluated the Contractor's provisions to assess organizations, programs, projects, and processes and found them to be adequately addressed by various sections. Section 10.2.3, "Assessment Performance," requires "Assessments to ascertain the adequacy and effectiveness of compliance with procedures and processes developed to ensure nuclear and process safety...." Section 10.2.1, "Independent Assessment," identifies that the purpose of independent assessments is to verify implementation, effectiveness, and products and services that meet specified requirements. Section 1.2, "Purpose and Scope," states, "The QAP provides for technical oversight and independent assessment of project activities, consisting of design, procurement, site preparation, constructions, start-up, operations, deactivation, and administrative/records management." As noted above, section 10.2.1 states, "Assessments are performed in all areas where the requirements of the QAP apply."

The reviewers evaluated the Contractor's commitment to a performance-based approach to assessments^{3/4} with the expectation that compliance is the baseline. This commitment is adequately addressed in Section 10.2.3, which states, "Assessments to ascertain the adequacy and effectiveness of compliance with procedures and processes developed to ensure nuclear and process safety...." In addition, as noted above, Section 10.2.1 identifies that the purpose of an independent assessment is to verify implementation, effectiveness, and products and services that meet specified requirements.

The reviewers evaluated the Contractor's provisions for an overall plan for independent assessments that considers previous performance, time-dependent activities, risk, and contribution to safety and product quality. The reviewers did not have access to the Contractor's specific plan for assessments but found this adequately addressed in the text. Section 10.2.1 states, "They are regularly scheduled on the basis of the status and the safety significance of the activities being audited and/or assessed. Assessments are initiated early enough to ensure the implementation of an effective QAP." Section 10.2.1 also states, "The scheduling of independent assessments and allocation of resources shall be based on work scope, work status, relative importance to safety, and the complexity of the activity being assessed." The Plan does not specifically address the issue of allowing previous performance to be a consideration in establishing the frequency of assessments.

The reviewers evaluated the Contractor's provisions to allow multiple methods for conducting independent assessments that include such mechanisms as inspections, peer reviews, technical reviews, audits, and surveillance. These provisions are adequately addressed in Section 10.2.1, which states, "Independent assessments include performance of technical and QA audits, inspections, surveillances, and laboratory performance."

The reviewers evaluated the Contractor's provisions to require the assessments to be performed according to a written procedure that requires results to be documented and shared with appropriate levels of management who can take meaningful corrective action. This is adequately addressed in Section 10.2.4, "Assessment Results and Reports," which states, "The results of assessments shall be documented and reported to appropriate levels of management within the project organization. Adequate information shall be documented so that meaningful actions can be taken." Section 10.2.1 identifies that "Assessments are conducted in accordance with approved procedures and documented in a report to management."

The reviewers evaluated the Contractor's provisions for requiring the verification of the adequacy of corrective actions, including actions identified to prevent reoccurrence or otherwise improve performance. This subject is adequately addressed in Section 10.3, "Responsibilities," which identifies the QA Manager as responsible for "evaluating the adequacy of management responses to assessment deficiencies and conducting follow-up evaluations to verify that corrective actions have been accomplished as scheduled." Section 10.2.1 requires "QA personnel shall ...perform follow-up and verification of actions taken." Section 10.2.1 also states, "Assessments are conducted to ...verify the timely implementation, adequacy, and effectiveness of corrective action."

The reviewers evaluated the Contractor's provision for tracking identified action items to resolution and to determine if similar deficiencies exist elsewhere. Implementing procedures were not available to determine if the responsible manager is required to evaluate for the possibility of the same/similar deficiency in other areas. In Section 3.2.1, the Contractor adequately addresses the issue of requiring identified action items to be tracked to resolution.

The reviewers evaluated the Contractor's provisions for sharing lessons learned from the assessment to be communicated to other organizations with similar activities. These provisions are adequately addressed in Section 10.2.5, which indicates management is responsible for considering sharing results as a lessons learned. Section 3.2.2, "Corrective Action," also addresses trend reports and how they are issued to project management and working level personnel as tools in identifying potential improvements.

2. The reviewers evaluated the Contractor's provision for staff that performs independent assessments to have sufficient freedom from the line to carry out the responsibilities. This is adequately addressed in Section 10.2.2, which states, "Personnel that conduct assessments shall not be directly responsible for the work processes and systems being assessed."

The reviewers evaluated the Contractor's provision to make certain that the assessing organization reports to a sufficiently high level in the organization to ensure organizational independence and access to appropriate levels of authority. The reviewers were not provided a detailed organization chart that indicated the reporting relationship. However, this issue is adequately addressed in Section 1.2, which states, "Personnel performing assessments have direct access to the Project Manager when necessary to ensure that appropriate actions can be effected."

3. The reviewers evaluated the Contractor's provisions to require personnel conducting assessment to be qualified and knowledgeable. This issue is adequately addressed in Sections 10.2.1 and 10.2.2. Section 10.2.1 states, "Assessments are lead by appropriately qualified and certified audit personnel and supported by qualified technical personnel." Section 10.2.2 requires "Personnel that conduct audits shall meet the requirements described in paragraphs 3.1 through 3.4 of NQA-1, Supplement 2S-3 (1994)." In addition, Section 2.2 requires "Personnel certification is required for performing the following: Independent assessments and audits."

The reviewers evaluated the Contractor's provisions to require assessment personnel to have the necessary technical knowledge to accurately observe and evaluate activities. This issue is adequately addressed in Section 10.2.1, which identifies "Assessments are lead by appropriately qualified and certified audit personnel and supported by qualified technical personnel."

4.3.10.3 Conclusion

On the basis of the evaluation described in this section, the reviewers concluded that the Contractor's Plan meets the contractual and regulatory requirements for independent assessments.

5.0 REFERENCES

10 CFR 830.120, "Quality Assurance Requirements," *Code of Federal Regulations*, as amended.

Quality Assurance Program and Implementation Plan, BNFL-5193-QAP-01, Rev. 0, BNFL Inc., 1998.

DOE/RL-96-0003, *DOE Process for Radiological, Nuclear, and Process Safety Regulation of the RPP Waste Treatment Plant Contractor*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 1998.

DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the RPP Waste Treatment Plant Contractor*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 1998.

G-830.120-REV 0, *Implementation Guide for Use with 10 CFR 830.120, "Quality Assurance,"* Rev. 0, U.S. Department of Energy, 1994.

Integrated Safety Management Plan, BNFL-5193-ISP-01, Rev. 4, BNFL Inc., 1998.

RL/REG-96-01, *Guidance for Review of TWRS Privatization Contractor Quality Assurance Program*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1998.

RL/REG-96-01, *Guidance for Review of TWRS Privatization Contractor Quality Assurance Program*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 2000.

RL/REG-98-13, *DOE Regulatory Unit Evaluation Report of the BNFL Inc. Quality Assurance Program and Implementation Plan*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1998.

RL/REG-2000-14, *Quality Assurance Program and Implementation Planning Handbook*, U.S. Department of Energy, Richland Operations Office, Rev. 0, 2000.

Safety Requirements Document (SRD), BNFL-5193-SRD-01, Volumes I and II, Rev. 2, BNFL Inc., 1998.

6.0 LIST OF TERMS

CAMS	Corrective Action Management System
CFR	Code of Federal Regulations
DOE	U.S. Department of Energy
ER	Evaluation Report
LCAR	Limited Construction Authorization Request
M&TE	measuring and test equipment
QA	quality assurance
QAP	Quality Assurance Program
QC	quality control
QL	Quality Level
RU	Regulatory Unit
RPP-WTP	River Protection Project-Waste Treatment Plant
SSCs	structures, systems, and components

Appendix A. Review Questions

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-01	Date Opened:
Check if answering “yes”: Protected Information? ____ Proprietary Information? ____ Team Accepted? ____	Date to Contractor:
	Date of Response:
	Date Closed:
Reviewer:	
Section: Introduction	
Description: The last paragraph of the “Introduction” states the following: “This quality assurance document consists of the Quality Assurance Policy, the Quality Assurance Program and the Quality Assurance Program Implementation Matrix (Implementation Plan) as Appendix A.” For consistency with the fifth paragraph of Section 1.3.3, reword the paragraph to read: “This quality assurance document consists of the Project Quality Policy, a description of the RPP-WTP Quality Assurance Program and the Quality Assurance Program Implementation Matrix (Implementation Plan) as Appendix A,” or provide additional explanation for the current wording.	
Contractor Response:	
Disposition:	

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-02	Date Opened:
Check if answering "yes":	Date to Contractor:
Protected Information? ____	Date of Response:
Proprietary Information? ____	Date Closed:
Team Accepted? ____	
Reviewer:	
Section: 1.2	
<p>Description:</p> <p>The second paragraph of Section 1.2, "Purpose and Scope," states, "The QAP reflects the quality requirements of 10 Code of Federal Regulations (CFR) Part 830.120, Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for Tank Waste Remediation (TWRS) Privatization Contractors (DOE-RL, 1996), Guidance for Review of TWRS Privatization Contractor Initial Quality Assurance Program, RL/REG-96-01, RPP-WTP quality policies, and defines their applicability to project work performed by the project functional groups consisting of technical, construction, administrative, operations, management, and subcontractors."</p> <p>The correct title of the reference for RL/REG-96-01 is <i>Guidance for Review of TWRS Privatization Contractor Quality Assurance Program</i>. Delete the word "Initial" from the title of this reference document, or provide additional explanation for the current wording.</p>	
Contractor Response:	
Disposition:	

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-03	Date Opened:
Check if answering "yes":	Date to Contractor:
Protected Information? ____	Date of Response:
Proprietary Information? ____	Date Closed:
Team Accepted? ____	
Reviewer:	
Section: 1.3	
<p>Description:</p> <p>Section 1.3, "Requirements and Structure," has been changed to state the following: "The implementation and maintenance of the QAP shall comply with the applicable elements of the following QA requirements: . . . 10 CFR 830.120 . . ."</p> <p>This statement is misleading. The requirements of 10 CFR 830.120 apply to all structures/items/activities that are within the scope defined by 10 CFR 830.1. Although specific quality elements defined in 10 CFR 830.120 may not apply to every activity, this is a function of the activity and is not based on a determination of the Contractor. The statement in the QAP creates the impression that compliance with 10 CFR 830.120 is optional. It is not.</p> <p>Reword this sentence as follows or provide additional explanation for the current wording: "The implementation and maintenance of the QAP shall comply with 10 CFR 830.120 and the applicable elements of the following QA requirements:"</p>	
Contractor Response:	
Disposition:	

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-04	Date Opened:
Check if answering "yes":	Date to Contractor:
Protected Information? ____	Date of Response:
Proprietary Information? ____	Date Closed:
Team Accepted? ____	
Reviewer:	
Section: Table 1-1	
<p>Description:</p> <p>It appears that Table 1-1, Compliance Table-ASME NQA-1 and DOE/RW-0333P vs. Quality Assurance Program, Rev. 5, should be corrected as follows:</p> <ul style="list-style-type: none"> • Add Section 2 to the QAP column for the "Quality Assurance Program" line. • The QAP column for the "Instructions, Procedures, and Drawings" line should be changed to Sections 4.2.1 and 5.3.2. • Add Section 5.3.5 to the QAP column for the "Control of Measuring and Test Equipment" line. • Delete Section 4.2.1 from the QAP column for the "Procurement Document Control" line • The reference to DOE/RW-0333P should be deleted from the (*) note at the bottom of the table. (The Quality Assurance Requirements Document [QARD] is not divided into basic and supplementary requirements.) <p>Modify this table to address the above, or explain why the current entries are correct.</p>	
Contractor Response:	
Disposition:	

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-05	Date Opened:
Check if answering "yes":	Date to Contractor:
Protected Information? ____	Date of Response:
Proprietary Information? ____	Date Closed:
Team Accepted? ____	
Reviewer:	
Section: 1.3.1	
<p>Description:</p> <p>The first paragraph of Section 1.3.1, "Classification of Items," states the following: "The QAP shall be applied to SSCs, activities, and services that have been determined to be important to safety or have attributes requiring quality criterion such as product quality affecting requirements." However, this section is devoted almost exclusively to the classification of SSCs and does not contain an adequate discussion of the classification of activities and services, particularly those construction activities and services that are important to safety or could impact safety.</p> <p>How is a determination of importance to safety made for construction activities and services?</p> <p>Into what safety categories are construction activities and services classified based on their importance?</p> <p>What Quality Levels apply to these safety categories?</p> <p>What quality requirements apply to construction activities and services deemed important to safety?</p>	
Contractor Response:	
Disposition:	

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-06	Date Opened:
Check if answering "yes":	Date to Contractor:
Protected Information? ____	Date of Response:
Proprietary Information? ____	Date Closed:
Team Accepted? ____	
Reviewer:	
Section: 1.3.1	
<p>Description:</p> <p>In Section 1.3.1, "Classification of Items," the following text has been added to the paragraph entitled "Quality Level 2 (QL-2)*": "Requirements, consisting of sound commercial practices and compliance with applicable industry codes and standards with additional specific quality assurance requirements as specified."</p> <p>It is not clear from the location of this statement within the paragraph whether it is intended to apply to Quality Level 2 SSCs in general, or be a footnote that only applies to dedicated commercial grade SSCs Important to Safety. To what extent is this statement intended to replace the application of 10 CFR 830.120 requirements to Quality Level 2 SSCs that are not dedicated commercial grade items? Clarify the intended purpose of this statement through appropriate footnote(s) or other changes to the text. For example, this could be simply clarified in the following manner:</p> <ul style="list-style-type: none"> • Move the asterisk from its present location at the end of "Quality Level 2 (QL-2)*" to the end of the statement "QL-2 SSCs may include Dedicated Commercial Grade SSCs*" • Provide the following explanation of the asterisk at the bottom of the page in the normal location for a footnote: "*For Dedicated Commercial Grade SSCs ITS, requirements consist of sound commercial practices and compliance with applicable industry codes and standards with additional specific quality assurance requirements as specified." 	
Contractor Response:	
Disposition:	

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-07	Date Opened:
Check if answering "yes":	Date to Contractor:
Protected Information? ____	Date of Response:
Proprietary Information? ____	Date Closed:
Team Accepted? ____	
Reviewer:	
Section: 1.3.1	
<p>Description:</p> <p>Section 1.3.1 of the QAP, "Classification of Items," discusses importance to safety in terms of safety design class and safety design significant classifications.</p> <p>Section 1.2.1 of the Limited Construction Authorization Request (LCAR) discusses importance to safety from the standpoint of seismic category and performance category classifications.</p> <p>There is no information in either document to explain the relationship, if any, between these two sets of classification criteria. Explain how items are classified based on their importance to safety.</p>	
Contractor Response:	
Disposition:	

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-08	Date Opened:
Check if answering "yes":	Date to Contractor:
Protected Information? ____	Date of Response:
Proprietary Information? ____	Date Closed:
Team Accepted? ____	
Reviewer:	
Section: 1.3.2 and Table A-1	
<p>Description:</p> <p>Section 1.3.2, "Graded Approach," provides a brief description of the graded approach but does not specifically identify how the graded QA process will be implemented. Use of a graded approach is required by 10 CFR 830.7.</p> <p>Given the requirements of 10 CFR 830.120(b)(1) that the QAP must include a discussion of how the requirements are complied with, expand the discussion of the graded approach to more completely address the implementation of 10 CFR 830.7.</p>	
Contractor Response:	
Disposition:	

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-09	Date Opened:
Check if answering "yes":	Date to Contractor:
Protected Information? ____	Date of Response:
Proprietary Information? ____	Date Closed:
Team Accepted? ____	
Reviewer:	
Section: Figure 1-1	
<p>Description:</p> <p>Figure 1-1, RPP-WTP Quality Program, appears to be incorrect in that:</p> <ul style="list-style-type: none"> • The QARD Matrix is part of the QA Provisions Document and not the QAP Description. • If Figure 1-1 is meant to depict the document hierarchy, the QA Provisions Document should be placed below the QAP. <p>Revise Figure 1-1 or provide additional explanation of the figure.</p>	
Contractor Response:	
Disposition:	

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-10	Date Opened:
Check if answering "yes":	Date to Contractor:
Protected Information? ____	Date of Response:
Proprietary Information? ____	Date Closed:
Team Accepted? ____	
Reviewer:	
Section: 2.2	
<p>Description:</p> <p>The last sentence of the third paragraph of Section 2.2, "Requirements," states, "Construction craft qualification by trade or labor agreement requirements is a basic premise for employment." In other places in this section of the QAP (e.g., first paragraph), the Contractor commits to verifying experience and education of employees.</p> <p>10 CFR 830.120(c)(1)(ii), "Personnel Training and Qualification," states, "Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained."</p> <p>Will the experience/certification/qualifications of personnel supplied by the labor union be verified and what information will be retained for the project records?</p>	
Contractor Response:	
Disposition:	

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-11	Date Opened:
Check if answering "yes":	Date to Contractor:
Protected Information? ____	Date of Response:
Proprietary Information? ____	Date Closed:
Team Accepted? ____	
Reviewer:	
Section: 9.3	
<p>Description:</p> <p>In paragraph 5 of Section 9.3 of the QAP, who is "senior management" that has the overall responsibility for the planning and performance of management assessments? This section does not identify what the Contractor does to execute these responsibilities. In addition, this responsibility is not addressed in Section 9.4, where the responsibilities are identified. How does this correlate with Section 9.3, paragraph 2, which states, "Managers at every level shall periodically assess the performance of their organization?"</p>	
Contractor Response:	
Disposition:	

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-12	Date Opened:
Check if answering "yes":	Date to Contractor:
Protected Information? ____	Date of Response:
Proprietary Information? ____	Date Closed:
Team Accepted? ____	
Reviewer:	
Section: 5.3.1	
<p>Description:</p> <p>10 CFR 830.120(b)(1) states, "A QAP shall include a discussion of how the criteria of paragraph (c) of this section will be satisfied."</p> <p>The level of detail provided in Section 5.3.1, "Project Management and Planning," is not sufficient to comply with the 10 CFR 830.120(b)(1) requirement. In addition, Table A-1, "Quality Assurance Program Implementation Matrix," does not include a reference to a procedure on work planning. Although Section 5.3.1 discusses the development of work control documents, there are a number of items that should be addressed in those work controlling documents. An example of these items is as follows:</p> <ul style="list-style-type: none"> • Ensuring qualified personnel accomplish the work • Ensuring that personnel take responsibility for the quality of their own work • Ensuring that the personnel follow prescribed standards, procedures, or instructions. <p>Expand the description, provide a reference to a work planning procedure, or explain why the current description complies with the 10 CFR 830.120 requirement.</p>	
Contractor Response:	
Disposition:	

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-13	Date Opened:
Check if answering "yes":	Date to Contractor:
Protected Information? ____	Date of Response:
Proprietary Information? ____	Date Closed:
Team Accepted? ____	
Reviewer:	
Section: General	
<p>Description:</p> <p>There is no reference within the QAP to the June 26, 2000, Contractor LCAR submittal, which discusses the methods and systems to be used during the limited construction phase of work. In addition to identifying the activities that could impact Important to Safety SSCs, the LCAR submittal also discusses the controls that are applied to these activities to achieve quality.</p> <p>Include a reference in the QAP to the LCAR submittal or explain why this is not appropriate.</p>	
Contractor Response:	
Disposition:	

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-14	Date Opened:
Check if answering "yes":	Date to Contractor:
Protected Information? ____	Date of Response:
Proprietary Information? ____	Date Closed:
Team Accepted? ____	
Reviewer:	
Section: General	
<p>Description:</p> <p>The following statements have been added to Section 1.3.1, "Classification of Items": "QL-1 SSCs may include Dedicated Commercial Grade SSCs . . . QL-2 SSCs may include Dedicated Commercial Grade SSCs."</p> <p>In addition, the first paragraph of Section 7.3, "Dedicated Commercial Grade Items," has been changed to allow the use of dedicated commercial grade items for Important to Safety or product quality SSCs.</p> <p>The measures described in Section 7.3 and elsewhere in the QAP are insufficient to ensure that QL-1 and QL-2 SSCs that include commercial grade items will perform their intended function and meet design requirements. For example, the QAP does not require documentation of the characteristics of dedicated commercial grade items to be verified for acceptance or the acceptance criteria for those characteristics.</p> <p>Also, the QAP does not describe the methods to be used to provide reasonable assurance that dedicated commercial grade items will meet the acceptance criteria for those characteristics. Either delete the statements that have been added to Sections 1.3.1 and 7.3 or describe more fully the measures that will be used to effectively control dedicated commercial grade items.</p>	
Contractor Response:	
Disposition:	

RU Review Team Questions for RPP-WTP	
Question #: 00-QA-15	Date Opened:
Check if answering "yes":	Date to Contractor:
Protected Information? ____	Date of Response:
Proprietary Information? ____	Date Closed:
Team Accepted? ____	
Reviewer:	
Section: Introduction	
<p>Description:</p> <p>The third paragraph of the section entitled "Introduction" within the QAP states, in part, "This Quality Assurance Program has been developed as specified in Table S 4.1, Radiological, Nuclear, and Process Safety Deliverables for Part A and B to support the performance of Part B activities of the RPP-WTP Contract until the start of operations."</p> <p>The second paragraph of Section 1.0, "Introduction," within Appendix A makes a similar statement: "This QAP Implementation Plan describes how the criteria of 10 CFR 830.120 will be satisfied during Part B of the project and support the QAP, developed for the Part B activities until the start of operations."</p> <p>Consistent with the schedules and program scope in place at the start of planning for the evaluation, the RU's evaluation criteria addressed only elements of the QAP necessary for start of limited construction. The evaluation criteria were provided to the Contractor and to the public, stakeholders, and Tribal Nations, for information and comment before the start of the evaluation. These statements should be revised to reflect this restriction, or the Contractor should explain why revision is not necessary.</p>	
Contractor Response:	
Disposition:	

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Appendix B. Education and Expertise of the QA Team

Team Member	Education/Expertise
Stephen Byers	BS Electrical Engineering; more than 29 years of diverse experience related to QA, performance improvement, and engineering design/construction; 10 years experience as an electrical engineer in nuclear power plant design and construction; expert witness in litigation involving the quality of design and construction of nuclear power plants.
Thomas Colandrea	BS Metallurgical Engineering; MS Engineering Science and Metallurgy, MBA, PE (CA); ASQ Certified Quality Engineer, Reliability Engineer, and Quality Auditor; ANSI/ASME NQA-1 Lead Auditor; ASQ Fellow; more than 35 years experience in nuclear QA and metallurgical engineering.
Sandra English	BS Medical Technology; more than 20 years experience in the QA profession, including 12 years working with research and development efforts in various areas such as biology, atmospheric research, chemical analysis, and environmental remediation.
Albert Hawkins (Team Leader)	BS Chemical Engineering, MBA; more than 25 years experience in operations, oversight, safety, and QA; former manager of Compliance Assurance; former Director of Environment, Safety, Health and Quality Assurance.
Dennis Ryder	MS Science Education; over 22 years experience in QA, including providing quality engineering support to DOE organizations and contractors; participated as major contributor to the initial development of the Pacific Northwest National Laboratory's QA Program, including maintenance of the Lab's QA Program manuals and implementing procedures.
Cynthia Taylor (Assistant Team Leader)	BA in Business Management, MBA in Engineering Management and Technology; over 25 years experience in QA program development and project management; provided QA support to DOE, NRC, OCRWM, and DOD-regulated projects; performed international QA consulting and auditing; Certified ANSI/ASME NQA-1 Lead Auditor; Certified ISO 9001 Lead Assessor; Certified OCRWM Lead Auditor.

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